**4792. Ipecac root.** (F. D. C. No. 38051. S. No. 6-873 M.)

QUANTITY: 105 lbs. in 2 drums at Salt Lake City, Utah.

SHIPPED: 3-8-55, from New York, N. Y., by Smith Crude Drug & Spice Co.

LIBELED: 5-24-55, Dist. Utah.

CHARGE: 501 (d) (2)—the article was represented as *ipecac root*, and a substance other than ipecac root had been substituted in whole or in part for the article.

DISPOSITION: 7-29-55. Default—destruction.

## DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS*

**4793. Diabena.** (F. D. C. No. 34916. S. No. 57-490 L.)

QUANTITY: 795 16-fl. oz. btls. and 3 5-gal. btls. at Richmond, Va., in possession of Mrs. W. B. Wood, Jr., t/a C. D. Walker Co.

SHIPPED: On 8-25-50, during November 1950, and on unknown dates, from New York, N. Y.

LABEL IN PART: (Btl.) "Diabena - Alcohol 12½% Active Ingredients Tephrosiavirginiana, Lithii Citras, Cinnamon, Food Coloring. Dose: Two teaspoonfuls every four hours in water. Children in proportion to age. C. D. Walker Co. P. O. Box 1203 Richmond 9, Virginia."

ACCOMPANYING LABELING: Leaflets entitled "Diabena."

RESULTS OF INVESTIGATION: The article was shipped in bulk, and, upon its receipt by the consignee, a portion was relabeled and repackaged into the bottles.

LIBELED: 3-25-53; amended 4-15-53, E. Dist. Va.

CHARGE: 502 (a)—the labeling of the article while held for sale contained false and misleading representations that the article was an adequate and effective treatment for diabetes.

DISPOSITION: Mrs. W. B. Wood, Jr., claimant, filed an answer denying that the article was misbranded as alleged. On 5-8-53, the Government served interrogatories upon the claimant, who filed objections thereto with the court on 5-15-53. The court, after consideration of arguments of counsel, sustained the claimant's objections on 5-27-53. Subsequently, the Government filed a request for admissions to which the claimant objected. The claimant's objections were upheld in part. The case was tried before the court on 9-9-54, and on 3-23-55, the court handed down findings of fact and conclusions of law, holding, in effect, that the Government failed to prove by a preponderance of the evidence that the labeling claims were false and misleading.

The Government filed a notice of appeal to the United States Court of Appeals for the Fourth Circuit; and, on 11-7-55, after consideration of argument and briefs of counsel, the following opinion was handed down by that court:

DOBIE, *Circuit Judge:* "This case arose on a libel of information filed in the Eastern District of Virginia, under Section 304 (a) of the Federal Food, Drug, and Cosmetic Act, 21 U. S. C. 334 (a), praying seizure and condemnation of an article of drug known as 'Diabena.' The libel alleged that the drug had been shipped in interstate commerce; that certain descriptive literature became associated with it after its interstate shipment; and that it was misbranded and subject to condemnation because this accompanying labeling falsely represented that the drug would be effective in the treatment of diabetes (21 U. S. C. 352(a)).

"After the seizure, Mrs. W. B. Wood, Jr., appeared as claimant and filed an

*See also Nos. 4782-4784, 4788-4790.

answer admitting all of the essential allegations of the libel, except that the labeling statements were false or misleading. The case was tried by the District Judge without a jury. The sole question was that of the efficacy of 'Diabena' in the treatment of diabetes.

"The critical findings of the District Judge were:

> 10. The Government failed to prove by a preponderance of the evidence its charges that the labeling claims are false and misleading. Its experimental evidence consisted only of animal studies, in which the drug failed to reduce the blood sugar in some of the test rabbits; it had no clinical experiments in which the drug was tested on man. Instead, it relied on the opinions of a medical doctor and a pharmacologist who stated the drug would not prevent, cure, or mitigate diabetes but further stated that they were not familiar with the drug nor had they ever tested or used it, and that insulin, which 'Diabena' does not contain, is the best remedy for the disease known to medical science at the present time.
>
> 11. Without the results of actual use of the drug on patients with diabetes, I am unable to find that the Government has proved its case.
>
> 12. In order to show that the drug is not effective as claimed to be, it must be proved that the drug was given to patients in accordance with its directions and at different levels of dosage, in order to give it a fair trial.

"The Government has appealed to us from the District Judge's order dismissing the libel. We think the order of the District Court is clearly erroneous and must, therefore, be reversed.

"Claimant called no witnesses to testify that 'Diabena' is effective in the treatment of diabetes. See, United States v. 50 etc. bottles of Sulfa-Seb, 54 F. Supp. 759, 763. There was stipulated into the record the affidavit of Dr. Thompson and statements of clinical records (which had been filed with the patent papers) which indicated that 'Diabena' had been effective in the treatment of certain diabetics. These seem to have impressed the District Judge, though he expressly stated: 'My opinion is based upon the lack of evidence on the part of the Government to show that it ("Diabena") is not effective.' It is clear that the granting of the patent gives no right of misrepresentation, but it merely restrains others from manufacturing, using or selling what is covered by the patent. Decker v. Federal Trade Commission, 176 F. (2d) 461, 463, cert. denied 338 U. S. 878.

"It is well settled that seizures under the Federal Food, Drug and Cosmetic Act are civil in nature. The Government need prove its case only by a preponderance of the evidence. United States v. 5 Cases, 'Figlia Mia Brand' Vegetable Oils, 179 F. (2d) 519, cert. denied 339 U. S. 963; C. C. Company v. United States, 147 F. (2d) 820.

"To show that 'Diabena' is worthless in the treatment of diabetes, the Government introduced three expert witnesses, who testified at some length. The qualifications and competence of these witnesses was not open to question.

"Dr. Henry St. George Tucker, Jr., is a practising physician and an Associate Professor of Medicine at the Medical College of Virginia, who has specialized in the treatment of diabetes. In no uncertain terms, he testified that the only means of keeping diabetes under control are the reduction of carbohydrates in the diet and the injection of insulin; that, in spite of many attempts, no successful oral treatment of diabetes has ever been found. He further stated that in his opinion, which was the consensus of modern medical opinion, a drug containing the ingredients of 'Diabena' would have no value whatever in the treatment of diabetes, and that these ingredients have been totally discarded in the treatment of diabetes.

"Dr. Haag is Professor of Pharmacology at the Medical College of Virginia. His specialty has been the study of drugs and their therapeutic uses in connection with the human body. Dr. Haag said that in his opinion, based upon his training and experience as a pharmacologist, an article having the ingredients of 'Diabena' would have no effect in the treatment of diabetes or the lowering of blood sugar. He then described the known effects and uses for the ingredients of 'Diabena.' The principal ingredients of 'Diabena' are Tephrosia Virginiana (also known as Devil's Shoestring, Wild Sweetpea and Goat's Rue), lithic citras, cinnamon and food coloring. Tephrosia, he said, is a vermifuge (a product used to expel worms from the gastrointestinal tract) and tends to increase sweating; lithium citrate has no medical use; cinnamon is merely a flavoring.

On cross-examination, Dr. Haag admitted that he had not administered 'Diabena' to any patients.

"The final witness for the Government was Dr. Robert L. Grant, a pharmacologist employed by the Food and Drug Administration, who since 1941 has been engaged in testing the action of insulin and other drugs which might affect the level of blood sugar. He testified about experiments which he conducted with 'Diabena' by administering it to rabbits, the official test animal for insulin in the United States Pharmacopoeia. He stated that the tests on 'Diabena' were the best he could devise and were the same as those conducted to determine the effectiveness of insulin or any other drug to show its effect on diabetes or the lowering of blood sugar. Dr. Grant explained that a drug which would reduce the level of blood sugar in rabbits would reduce the level of blood sugar in human beings; and that the results of his tests showed that 'Diabena' had no more effect on the lowering of blood sugar than did water.

"The applicable law of this case has been rather clearly set out in two leading cases. In United States v. One Device Intended for Use as a Colonic Irrigator, 160 F. (2d) 194, 199, Circuit Judge Huxman stated:

> That these medical experts were competent and qualified to testify as to the matter in issue is clear. They were not disqualified merely because they had not seen it in operation. They testified not only that they were conversant with colonic irrigation, but also that they were familiar with the principles of the particular device in question. * * * Being fully conversant with the principles of colonic irrigation and with the principles upon which this device operated, the testimony of these medical experts was competent and constituted substantial evidence.

And in Neff v. Federal Trade Commission, 117 F. (2d) 495, 497, Circuit Judge Soper (speaking for our Court) said:

> The actual question now presented is whether the testimony of the six experts who testified for the Commission can be considered substantial evidence in view of their lack of actual experience in the use of the petitioner's preparation, as compared with the conflicting statements of doctors who had administered Glantex to their patients. We think the evidence is sufficient to support the Commission's finding. All of the experts were well qualified to speak upon the subject; and their opinions, though based only upon their general medical and pharmacological knowledge, constituted substantial evidence tending to show that the representations of the petitioner were not justified.

"In Wigmore on Evidence, Vol. III, page 3, Section 687, we find:

> To deny the competency of a physician who does not know his facts from personal observation alone is to reject medical testimony almost in its entirety. To allow any physician to testify who claims to know solely by personal experience is to appropriate the witness-stand to impostors. Medical science is a mass of transmitted and collated data from numerous quarters; the generalizations which are the result of one man's personal observation exclusively are the least acceptable of all. The law must recognize the methods of medical science. It cannot stultify itself by establishing, for judicial inquiries, a rule never considered necessary by the medical profession itself. It is enough for a physician, testifying to a medical fact, that he is by training and occupation a physician; whether his source of information for that particular fact is in part or entirely the hearsay of his fellow-practitioners and investigators, is immaterial.

"See, also, Irwin v. Federal Trade Commission, 143 F. (2d) 316; John J. Fulton Co. v. Federal Trade Commission, 130 F. (2d) 85, cert. denied 317 U. S. 679; Dr. W. B. Caldwell, Inc. v. Federal Trade Commission, 111 F. (2d) 889.

"As to the consensus of present-day medical opinion as a fact, see, United States v. Kaadt, 171 F. (2d) 600; Research Laboratories, Inc. v. United States, 167 F. (2d) 410, cert. denied 335 U. S. 843. Experiments with animals have been held to be valid in showing the physiological effects of drugs on human beings, United States v. Lesser, 66 F. (2d) 612.

"Finally, we observe that it might indeed be difficult to find a diabetic who would act as a guinea-pig by abandoning insulin over any substantial period of time and submitting to treatment by 'Diabena' or any other drug whose efficiency has not been established. Diabetes is a serious disease which, if not properly and promptly treated, tends to become increasingly dangerous. Indeed, Dr. Tucker unhesitatingly testified that if a person suffering from diabetes is deprived of insulin, serious consequences might well follow.

"We think the Government has clearly established its case by a preponderance of the evidence. The judgment of the District Court is, accordingly, reversed and the case is remanded to that court with instructions to enter judgment in favor of the United States."

The case was remanded to the United States District Court for the Eastern District of Virginia; and, on 3–22–56, the court ordered the product destroyed.

**4794. Reclu capsules.** (F. D. C. No. 37111. S. No. 40–270 L.)

QUANTITY: 12 100-capsule btls. at Phoenix, Ariz.

SHIPPED: 7–28–54 and 9–4–54, from Fullerton, Calif., by Reclu Co.

LABEL IN PART: (Btl.) "Reclu Caps Each Capsule Contains Approx. 0.58 Grams Of A Specially Prepared Concentrate Made From Fresh Cabbage, Dessicated At Low Temp. * * * Reclu's Cabbage Concentrate Diet for Peptic Ulcers."

LIBELED: 9–30–54, Dist. Ariz.

CHARGE: 502 (a)—the bottle label of the article when shipped contained false and misleading representations that the article was an adequate and effective treatment for peptic ulcers.

DISPOSITION: 11–24–54. Default—destruction.

**4795. Trumac tablets.** (F. D. C. No. 36865. S. No. 90–431 L.)

QUANTITY: 10 cases, 12 btls. each, at Kansas City, Kans.

SHIPPED: 5–11–54, from Detroit, Mich., by Cemac Laboratories, Inc.

LABEL IN PART: (Btl.) "100 Tablets Trumac Tablets Enteric Coated Improved For the palliative relief of pain (headache) associated with Sinus Conditions, Facial Neuralgia, and Simple Headache. Contains: Salicylamide, as the active ingredient; with a catalytic agent CS 210 in a specially prepared base."

ACCOMPANYING LABELING: A flier designated "SINUS? . . . get palliative relief with TRUMAC TABLETS"; a leaflet designated "Are You A SINUS Victim?"; and placards designated "Are You a Sinus Victim? Ask About The New Tablet Treatment TRUMAC TABLETS"; and "TRUMAC TABLETS For the Palliative Relief of Pain Associated with Sinus Conditions."

LIBELED: 7–8–54, Dist. Kans.

CHARGE: 502 (a)—when the article was shipped, its bottle label and accompanying labeling contained false and misleading representations that the article was an adequate and effective treatment for sinus conditions.

DISPOSITION: 10–12–54. Default—destruction.

**4796. Artritina tablets.** (F. D. C. No. 37298. S. No. 40–268 L.)

QUANTITY: 48 100-tablet btls. at Phoenix, Ariz.

SHIPPED: 2–11–54, from Los Angeles, Calif., by Los Angeles Pharmacal Co.